

## **REMARKS**

Claims 1-23 are pending in the application. Claims 1, 9-12 and 18-20 have been amended. No new matter has been added.

### **Amendment to the Specification**

The first paragraph of the Specification has been amended to insert the patent number for parent application.

### **Declaration and Power of Attorney**

Enclosed is a properly executed copy of the Declaration and Power of Attorney from the parent application.

### **Objections to Claims 11, 12 and 18**

Claims 11 and 18 have been amended to correct the typographical errors noted by the Examiner.

Claims 11 and 12 have been amended to clarify the claims. These claims simply provide more detail regarding partner 2 of pair 1 and partner 2 of pair 2. Thus Applicants respectfully submit that the claims are in the proper dependent form, and request that the objection be withdrawn.

### **Rejections pursuant to 35 U.S.C. § 112, second paragraph**

Claims 1 and 18 stand rejected under 35 U.S.C, § 112, second paragraph, as vague and indefinite because, according to the Examiner, the claims do not identify how the reagents will

interact in order to determine the analyte of interest. The Examiner has also suggested that the claims be amended to include a negative limitation to clarify that partner 2 of pair 1 and partner 2 of pair 2 are not immobilized on the element.

Claim 1 has been amended to more clearly recite that both partner 2 of pair 1 and partner 2 of pair 2 bind to the analyte before the sample is added to the element. The claim has also been amended to recite that these partners are not immobilized on the material of the element. Accordingly, Applicants respectfully submit that claim 1 is now definite and request that the rejection be withdrawn.

With regard to claim 18, Applicants have amended the claim to clarify that the “substance derived from and representing the analyte” comprises partner 2 of pair 1 and partner 2 of pair 2 “bound to the analyte.” The claim also now includes the negative limitation that these partners are not present on the element before the substance is added to the element. Accordingly, Applicants respectfully submit that claim 18 is now definite and request that the rejection be withdrawn.

Claims 9 and 10 have been amended to remove the term “preselected.” Accordingly, Applicants respectfully submit that the claims are now definite and request that the rejection be withdrawn.

Claims 19 and 20 have been amended to change “carries” to “comprises.” Accordingly, Applicants respectfully submit that the claims are now definite and request that the rejection to be withdrawn.

Claims 5 and 6 have been rejected because of the phrase “direct label.” Applicants direct Examiner to paragraph [0024] of the specification for a description of “direct label.” In light of

the disclosure in ¶ [0024], Applicants respectfully submit that “direct label” is amply described in the specification. Therefore, Applicants respectfully request that the rejection be withdrawn.

Claims 1-22 stand rejected as being incomplete for omitting essential steps. Claims 1 and 18 have been amended to clarify that the analyte binds partner 2 of pair 2 and partner 2 of pair 1. With this amendment, and the other amendments to claims 1 and 18, Applicants respectfully submit that the claims are now definite and request that the rejection be withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1-23 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled. Applicants believe that with the amendment to claims 1 and 18, described above, that the rejection has been traversed. It is now clear in the claims that partner 2 of pair 1 and partner 2 of pair 2 bind the analyte, and that the complex is added to the sample application zone of the analytical element. The labeled partner 1 of pair 2, which is impregnated on the material so that it can be detached, binds to partner 2 of pair 2. This entire complex flows to the detection zone, where partner 2 of pair 1 binds to partner 1 of pair 1. All of these steps are now recited in independent claims 1 and 18. Accordingly, Applicants respectfully request that the rejection to claims 1-22 be withdrawn.

The Examiner has not recited any specific reasons for the rejection of independent claim 23. Therefore, Applicants have assumed that the Examiner meant to apply the rejection to claims 1-22 only. Therefore, Applicants request that the rejection to claim 23 be withdrawn.

## Rejections under 35 U.S.C. §102

Claims 1-3, 5-16, 18-20 and 23 stand rejected as anticipated by Pronovost *et al.* (WO 97/06439) and by Greenquist (U.S. Patent No. 4,806,311).

With regard to Pronovost *et al.*, Applicants have amended claims 1 and 18 at the Examiner's suggestion to recite the negative limitation that partner 2 of pair 1 and partner 2 of pair 2 are not present on the test strip (*i.e.*, the material enabling liquid transport). Pronovost *et al.* do not teach a method wherein two of the binding partners are not on the strip. Therefore, independent claims 1 and 18 recite components that are not taught in Pronovost *et al.*

With regard to claim 23, the analytical element "consist[s] essentially of" the "material enabling liquid transport" and binding partner 1 of pair 1 and partner 1 of pair 2. Therefore, it is clear that the analytical element of claim 23 is distinctly different than the device of Pronovost *et al.* because the device described in Pronovost *et al.* has additional binding partners present on the strip.

Turning now to Greenquist, this reference does not anticipate the present invention because Greenquist is completely different than the present invention. Greenquist teaches a method using a test strip with two or three layers: (1) a first reagent layer, (2) a second reagent

layer (optional), and (3) a detection layer (*see* column 5, lines 36 – 53, and column 10, line 64 through column 11, line 26). Greenquist also teaches a “label reagent” that comprises a label, at least one binding site for the analyte, and a ligand moiety (*see* col. 6, lines 19-21, and col 6, line 60 through col. 7, line 20). When one reagent layer is present on the strip, the reagent layer contains an immobilized form of the analyte, and the detection layer contains a binding substance for the label reagent (col. 8, lines 22 – 31). The label reagent and sample are added independently, or as a mixture, to the test strip (col. 8, lines 37 – 42). Thus, in Greenquist, when analyte is present in the sample, it binds to its binding partner on the label reagent. The label reagent is then free to migrate into the detection zone (col. 8, lines 42-47). When the test strip has two reagent layers, the label reagent is present in soluble form in the first layer and the second layer contains the immobilized form of the analyte (col. 10, line 64 through col. 11, line 16). Upon application of the sample, the sample contacts the label reagent and the analyte, if present, binds to the label reagent. (col. 11, lines 16-25).

Turning now to the present invention, independent claims 1, 18 and 23 are directed to the analytical element and a method of using the element where the element has a specific binding partner 1 of specific binding pair 1 (immobilized so that it binds partner 2 of pair 1), and a labeled partner 1 of specific binding pair 2 upstream of partner 1 of pair 1. Partner 2 of specific binding pair 2 is added to the sample, along with partner 2 of binding pair 1, before the sample is added to the strip. Analyte is detected by the binding of all of the binding partners and the analyte.

Greenquist is directed to a device and method that are different than the present invention because, in Greenquist, the label reagent includes both a binding partner for the analyte and a

ligand moiety that binds to its partner in the detection zone. No sandwich is formed in Greenquist as in the present invention. Further, if no analyte is present in Greenquist, the label reagent may bind in the reagent layer or the detection layer. On the other hand, in the present invention, labeled partner 1 of pair 2 becomes immobilized only in the presence of the analyte.

Since Greenquist describes completely different binding partners and operates in a completely different manner than the present invention, Greenquist does not teach each and every element of the present invention. Thus, Greenquist does not anticipate the present invention under 35 U.S.C. § 102. Accordingly, Applicants request that the rejection be withdrawn.

#### **Rejections under 35 U.S.C. § 103**

Dependent claims 4 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pronovost *et al.* or Greenquist in view of Onishi *et al.* (EP 0 328 106 A2). Examiner cites Onishi, *et al.* as teaching digoxin reagents in detection systems. Applicants respectfully traverse.

Claims 4 and 17 include all the limitations of claim 1. As discussed above, neither Pronovost *et al.* nor Greenquist anticipate claim 1. Thus, dependent claims 4 and 17 can not be obvious in view Onishi *et al.* since Onishi *et al.* only describes subject matter which Examiner considers relevant to claims 4 and 17.

Accordingly, Applicants request that the rejection under 35 U.S.C. § 103, based upon Onishi *et al.* in combination with Pronovost *et al.* or Greenquist be withdrawn.

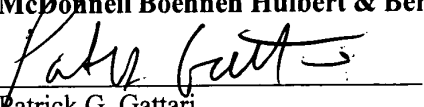
Claims 21 and 22 stand rejected under 35 U.S.C § 103(a) as being unpatentable over either Pronovost *et al.* or Greenquist in view of Friedman *et al.* (EP 0 630 974 A2). The Examiner cites Friedman *et al.* as teaching nucleic acid amplification and hybridization.

Applicants respectfully disagree with the rejection. Claims 21 and 22 include all the limitations of independent claim 18. As discussed above, neither Pronovost *et al.* nor Greenquist anticipate claim 18. Thus, dependent claims 21 and 22 can not be obvious in view Friedman *et al.* since Friedman only describes subject matter which Examiner considers relevant to claims 21 and 22.

Accordingly, Applicants request that the rejection under 35 U.S.C. § 103 based upon Friedman *et al.* in combination with Pronovost *et al.* or Greenquist be withdrawn.

#### CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference would expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

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